DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2005

Mr. John R. Miller
Director, Quality Assurance
and Regulatory Affairs
KaVo America
340 East Main Street
LAKE ZURICH IL 60047

Re: K050019
Trade/Device Name: In eXam Intraoral
Dental X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source
x-ray system
Regulatory Class: II
Product Code: EHD
Dated: January 4,2005
Received: January 5,2005

Dear Mr. Miller:

This letter corrects our substantially equivalent letter of January 31,2005, that contained an incorrect panel code for the In eXam Intraoral Dental X-ray System. The product code (EHD) was correct. It was the panel code (90) that was incorrect. Since we are in the process of deleting panel codes from substantially equivalent letters, we are revising this letter to reference only the product code.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number(if **known**): Not Assigned

Device **Name**: In eXam Intraoral Dental X-Ray System

Indications for Use:

The KaVo In eXam Intraoral X-ray device is to be used exclusively within dentistry as an extraoral source of x-rays.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___V___ OR Over-The-Counter Use _____
(Per 21CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050019

00039 (Replacement)

K050019

JAN 3 1 2005

510(k) Summary Statement for the KaVo In eXam Intraoral Dental X-Ray System

I General Information

Submitter: KaVo America
340 East Main
Lake Zurich, IL 60047

Telephone: (800) 323-8029 – Company Number
(847) 640-4924 – Contact Person

Fax: (847) 640-4970

Contact Person: John R. Miller
Director, Quality Assurance and Regulatory Affairs

Summary Preparation Date: December 7, 2004

II Names

Device Name: KaVo In eXam Intraoral Dental X-Ray System

Primary Classification Name: 90EHD – Unit, X-Ray, Extraoral with Timer

III Predicate Devices

- Gendex 765DC
- Planmeca Prostyle Intra
- Trophy Elitys

IV Product Description

The KaVo In eXam Intraoral Dental X-Ray System is an extraoral source of x-rays for imaging of the dento-maxilofacial area.

The KaVo In eXam Intraoral Dental X-Ray System is comprised of the following main components:

- X-ray tube head
- Yoke with user interface capabilities
- Articulated arm
- Horizontal arm
- Electronic control unit
- Wall mount
- Cone

The power supply is regulated to provide a fixed 70kVp, and the x-ray target current is fixed at 7mA. Predefined exposure times may be selected directly through the control or yoke switchpads. The range of expsure time is 0.012 through 1.88 seconds.

V Indications for Use / Rationale for Substantial Equivalence

The KaVo In eXam Intraoral Dental X-Ray System is to be used as an extraoral source of x-rays for imaging of the dento-maxilofacial area.

It shares the same indications for use, similar materials, design, operational, and functional features and therefore is substantially equivalent to the predicate devices listed in section III of this summary.

VI Safety and Effectiveness Information

Safety and Effectiveness is demonstrated by:
- Performance testing to meet product specifications
- Software testing to validate software design / performance
- Effective clinical image exposures
- Hazard analysis including risk level and solution
- Same indications for use as predicate devices.

All the above steps and evaluations combine to demonstrate that the Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System is safe and effective when the device is used as labeled.

VII Conclusion

The Gendex Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System was found to be is Substantially Equivalent to the predicate devices; the Pelton & Crane Orthophos Plus, the Planmeca PM 2002 CC Proline, the Instrumentarium Imaging Orthorpantomograph® OPD, and the Gendex Orthoralix SD2/Ceph and S/Ceph. The Gendex Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System shares the same indications for use, similar materials, design, operational, and functional features as the current marketed predicate devices. It has been shown to be safe and effective when used as labeled.